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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,280	05/27/2005	Jane Sanders	AATLP-001	1845

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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
04/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,280	SANDERS ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *121,126,127,129,130,133-137,198-202, 204-213* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/9/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 121,126,127,129,130,133-137,157-159,162-171,173-175,179,182-186,189-192,195,198-202 and 204-213.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 157-159,162-171,173-175,179,182-186,189-192 and 195.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/1/2009 has been entered.

Formal Matters

2. Claims 1-120, 122-125, 128, 131, 132, 138-156, 160, 161, 172, 176-178, 180, 181, 187, 188, 193, 194, 196, 197, 199, and 203 have been cancelled by Applicant. New claims 204-213 have been added. Claims 157-159, 162-171, 173-175, 179, 182-192, and 195 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 121, 126, 127, 129, 130, 133-137, 198-202, and 204-213 are under examination.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 10/9/2009 has been considered by the examiner. A signed copy is attached hereto.

Response to Arguments

Objections/Rejections Withdrawn

4. Rejections drawn to claims 122 and 203 are moot in light of Applicant's cancellation of these claims.

5. The rejection of claim 121 under 35 U.S.C. 102(b) as being anticipated by WO 91/09137 (published 27 June 1991, cited in Applicant's IDS of 7/20/2005), is withdrawn in light of Applicant's amendments.

6. The rejection of claims 121, 126, 127, 129, 130, 133, 136, 137, and 198 under 35 U.S.C. 103(a) as being unpatentable over WO 91/09137 (published 27 June 1991) and Van Der Heijden et al., (Clin Exp Immunol. 1999;118:205-212), as evidenced by UniProt, Accession No. P16473 (sequence version 1, 1 August 1990), Harlow et al., Eds. (Antibodies, A Laboratory Manual. Cold Spring Harbor Press. 1988,

and Kohn et al., (J Clin Endo and Metab. 1997;82(12):3998-4009), is withdrawn in light of Applicant's amendments.

7. The rejection of claims 200-202 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is withdrawn in light of Applicant's amendments.

8. The rejection of claim 202 is rejected under 35 U.S.C. 102(b) as being anticipated by Hoogemboom et al., US Patent 5,565,332 (15 October 1996), is withdrawn in light of Applicant's amendments.

9. The objection and indication of allowability but for being dependent on rejected claims, of claims 134, 135, 200, 202, 210, and 211 are withdrawn. New rejections are set forth below.

Claim Rejections/Objections Maintained

10. The provisional rejection of claims 121, 126, 127, 129, 130, 133, 136, 137, and 198 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 63-66 and 70 of copending Application No. 12/333,714, is maintained for the reasons of record and the reasons set forth herein.

In the Response filed 9/14/2009, Applicant argues that the instant case is the earlier filed case and that the provisional rejection should be withdrawn. Applicant argues that maintaining the rejection is inconsistent with MPEP 804(B) (Remarks, p. 16). Applicant's arguments have been fully considered, but they are not persuasive.

In the instant case, the provisional ODP rejection is not the only rejection remaining in the instant case. The claims at issue in the copending '714 case are pending and under examination. The instant provisional rejection must be maintained until such time as the instant claims are found allowable and the provisional ODP rejection is the only remaining rejection. Only in that event will the provisional rejection be withdrawn in light of the instant application being the earlier filed case. However, in the event that the copending '714 application is found to be in condition for allowance prior to the allowability of the instant application, a terminal disclaimer will be required in the instant case over the claims of the '714 application, should they remain obvious over the instant claims.

The examiner notes that this rejection was presented in the Office Action mailed 6/2/2009, but the last two digits of the serial number were inadvertently inverted. Applicant correctly identified the '714

application in the response filed 9/14/2009 and accordingly had sufficient notice of the copending application and provided an adequate response to the provisional rejection.

New Claim Rejections/Objections

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 121 and 198 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al., (J Biol Chem. 1988;263(31):16341-16347) (cited on Applicant's IDS of 10/9/2009).

Yoshida et al., teach TRMo-2, anti-TSH receptor human monoclonal antibodies that inhibit TSH binding to the TSH receptor and stimulate cAMP production by cells expressing the TSH receptor (abstract, p. 16344, column 2, first paragraph of Results; Figure 1(B); Figure 2(B)(a) and Figure 2(B)(b)).

Applicant provides preliminary arguments against the Yoshida reference, which was brought to the examiner's attention in the IDS filed 10/9/2009. Applicant provides an explanation of Yoshida at pp. 19-20 of the Remarks filed 10/9/2009. Applicant states that later published papers showed the antibodies reported in the Yoshida paper (among others) showed stimulating or blocking activity only at high concentrations and that they did not show any TSH competing activity (Remarks, p. 19). Applicant argues that the characteristics of the Yoshida antibodies are unsupported as evidenced by later filed papers (p. 20). Applicant's arguments have been fully considered, but the examiner could find no specific mention of any enabling argument directed specifically to the TRMo-2 antibody of Yoshida in the citations of the after-filed literature.

In the Request for Continuing Examination filed 1/14/2010, Applicant provides additional preemptory responses to a rejection over Yoshida et al. Applicant argues that a person skilled in the art would find the assertions in Yoshida as to the characteristics of the antibodies not to be credible (Remarks, p. 1). Applicant argues that Yoshida teaches four monoclonal antibodies to the TSH receptor (p. 3). Applicant argues that the methods used by Yoshida et al., to obtain these monoclonal antibodies would not reasonably be expected to achieve the stated results and that it cannot be concluded that the molecules reported to be monoclonal antibodies were actually monoclonal antibodies (Remarks, p. 2). Regarding the TRMo-2 antibodies, Applicant argues that the results of both inhibition and stimulation of

cAMP production are suspect because there is no indication as to how the reported results were obtained (Remarks, p. 4). Applicant argues that the skilled person is aware that in the absence of the details of experimental protocols, the conclusions drawn by Yoshida are not reliable (Remarks, p. 4).

As Applicant is aware, the Journal of Biological Chemistry is a highly reputable peer-reviewed scientific journal. The paper was reviewed by those of ordinary skill in the art and was published to the broader scientific community in 1988. If Applicant takes issue with the methods of Yoshida, such that Applicant argues the enablement of the prior art reference, it is incumbent on Applicant to provide evidence showing this insufficiency. Neither attorney argument nor a Declaration from the interested instant inventors will replace an evidentiary showing to this effect. Without an evidentiary showing, the examiner must rely on the data presented in the Yoshida reference as to the TRMo-2 antibodies. As stated above, the examiner could find no specific mention of any enabling argument directed specifically to the TRMo-2 antibody of Yoshida in the citations of the after-filed literature cited by Applicant.

13. Claims 126, 127, 129, 130, 133, 136, and 137 are rejected in addition to claims 121 and 198 under 35 U.S.C. 102(b) as being anticipated by Yoshida et al., (J Biol Chem. 1988;263(31):16341-16347) (cited on Applicant's IDS of 10/9/2009), for the reasons set forth above.

Yoshida et al., teach TRMo-2, anti-TSH receptor human monoclonal antibodies that inhibit TSH binding to the TSH receptor and stimulate cAMP production by cells expressing the TSH receptor (abstract, p. 16344, column 2, first paragraph of Results; Figure 1(B); Figure 2(B)(a) and Figure 2(B)(b)).

Claims 126, 127, 129, 130, 133, 136, and 137 are dependent claims that recite certain internal units of inhibitory activity or cAMP stimulatory activity.

Absent evidence to the contrary, the TRMo-2 antibodies taught by Yoshida et al., meet the limitations of the claims. Because the Patent Office does not have the facilities to determine whether the TRMo-2 antibodies comprise the respective activities using international standard units, the burden is on the application to show a novel and unobvious difference between the claimed human monoclonal antibodies those of Yoshida et al. See *In re Brown*, 59 CCPA 1036, 459 F.2d. 531, 173 USPQ 685 (CCPA 1972) (holding at 1041, "[a]s a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith") and *Ex parte Gray*, 10 USPQ 2d 1922, 1924-25 (PTO Bd. Pat. App. & Int.).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 204-209, 212, and 213 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al., (J Biol Chem. 1988;263(31):16341-16347) (cited on Applicant's IDS of 10/9/2009), UniProt, Accession No. P16473 (sequence version 1, 1 August 1990) (previously cited of record), Zhong et al., (Yan Ke Xue Bao. 2002 Sep;18(3):185-9, Abstract), and Kohn et al., (J Clin Endo and Metab. 1997;82(12):3998-4009) (previously cited of record), as evidenced by WO 91/09137 (published 27 June 1991) (previously cited of record).

The Examiner finds the following facts:

a. Yoshida et al., teach TRMo-2, anti-TSH receptor human monoclonal antibodies that inhibit TSH binding to the TSH receptor and stimulate cAMP production by cells expressing the

TSH receptor (abstract, p. 16344, column 2, first paragraph of Results; Figure 1(B); Figure 2(B)(a) and Figure 2(B)(b)).

b. Yoshida does not teach recombinant antibodies.

c. The amino acid sequence of human TSHR was well known in the art at the time of the instant invention. See UniProt, Accession No. P16473.

d. Zhong et al., teach the production of recombinant antibodies by sequencing monoclonal antibodies and fragments thereof, was known in the art prior to the instantly claimed invention.

e. Kohn et al., teach routine tests for cAMP activity, TSH binding to the TSH receptor, and binding affinity to the TSHR (abstract; Figure 1; p. 3999, column 2, last paragraph to p. 4000, column 1, first paragraph; p. 4000, column 2, fourth paragraph; p. 3998, column 2, last paragraph; Table 1, p. 4002; Figure 2, p. 4003; Table 2, p. 4004; Figure 3, p. 4004; Table 4, p. 4006; and Figure 5, p. 4006). Percent inhibition is also shown in a commercial TRAK assay in Table 3 (p. 4005) and Figure 4.

f. A person of ordinary skill in the art at the time of the instant invention would have been able to make recombinant antibodies by using well-known methodologies and protocols, such as the ones taught by the Zhong et al., using the well-know sequence of the TSHR and the TRMo-2 human monoclonal antibodies taught by Yoshida, and the resulting structure and function of the recombinant antibodies would have been predictable.

g. There was a recognized need in the art at the time the invention was made to generate recombinant antibodies that can be practically and cost-effectively used as diagnostics and as immunotherapetuics for thyroid-based autoimmune disorders such as Graves' disease and Hashimoto's thyroiditis, as evidenced by WO 91/09137, p. 3, line 25-33, p. 4, lines 31-34, and p. 5, lines 26-34).

h. At the time of the instant invention, there were a finite number of identified predictable potential solutions recognized in the art to solve the problem making find human antibodies that can be practically and cost-effectively used as diagnostics and as immunotherapetuics for thyroid-based autoimmune disorders such as Graves' disease and Hashimoto's thyroiditis, as evidenced by WO 91/09137, p. 3, line 25-33, p. 4, lines 31-34, and p. 5, lines 26-34).

In view of the facts recited above, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the prior art elements according to known methods to yield predictable results. A person of ordinary skill in the art at the time the invention was

made would have reasonably known that the production of recombinant antibodies by sequencing monoclonal antibodies and fragments thereof, was known in the art prior to the instantly claimed invention, see Zhong et al. Yoshida et al., teaches the starting material, human monoclonal antibodies with the claimed characteristics (TRMo-2 antibody). Yoshida does not teach recombinant antibodies. Zhong et al., teach the production of recombinant antibodies by sequencing monoclonal antibodies and fragments thereof, was known in the art prior to the instantly claimed invention. Additionally, the amino acid sequence of human TSHR was well known in the art at the time of the instant invention. A person of ordinary skill in the art at the time of the instant invention would have been able to make recombinant antibodies by using well-known methodologies and protocols, such as the ones taught by the Zhong et al., using the well-know sequence of the TSHR and the TRMo-2 human monoclonal antibodies taught by Yoshida, and the resulting structure and function of the recombinant antibodies would have been predictable. The rationale for making recombinant antibodies with the claimed characteristics is also found in the prior art. There was a recognized need in the art at the time the invention was made to generate recombinant antibodies that can be practically and cost-effectively used as diagnostics and as immunotherapetuics for thyroid-based autoimmune disorders such as Graves' disease and Hashimoto's thyroiditis, as evidenced by WO 91/09137. A person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense (see *KSR Int'l Co. v. Teleflex*, 550 US 389, 421, 82 USPQ2d 1385, 1397 (S.Ct. 2007).

Additionally, with regard to the inhibitory activity and affinity levels of the dependent claims, the Patent Office does not have the facilities to comparatively test recombinant antibodies or the starting material monoclonal antibodies taught Yoshida. Absent evidence to the contrary, the burden is on the application to show a novel and unobvious difference between the claimed TSHR binding partners activity and affinity levels and those of the prior art. See *In re Brown*, 59 CCPA 1036, 459 F.2d. 531, 173 USPQ 685 (CCPA 1972) (holding at 1041, "[a]s a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith") and *Ex parte Gray*, 10 USPQ 2d 1922, 1924-25 (PTO Bd. Pat. App. & Int.). Applicant's attention is also drawn to Kohn et al., which teaches routine tests for cAMP activity, TSH binding to the TSH receptor, and binding affinity to the TSHR.

Claim Rejections - 35 USC § 112, First Paragraph

Written Description

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 134, 135, 500-202, 210, and 211 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 19 USPQ2d 1111, (Fed. Cir. 1991), states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of the claim indicates that these claims are drawn to a genus, i.e., a genus of monoclonal antibodies or fragments of monoclonal antibodies or recombinant antibodies with a recited function, but only a partial structure disclosed.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required

to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states, "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

The instant claims recite antibodies with functional characteristics, but only limited partial structure. For example, claim 134 recites alternative structural embodiments where the VH domain may be SEQ ID NO: 1 or one or more VH CDRs from SEQ ID NO: 2, 3, or 4. No VL domain is recited in the claim and the limited alternative embodiments of the structure of the VH domains, which are, in the alternative, limited to only one CDR, do not adequately describe the structure of the claimed genus of antibodies. Claim 200, for example only describes a VH domain and no VL domain is disclosed. Claims 201 and 202 recite one or more VL or VH CDRs, but not both, and not all of the CDRs, including CDR3, which is know to be critical for binding, are disclosed. This results in an incomplete structural description of the claimed genus of antibodies and this structural insufficiency results in an inadequate description of starting material, such that one of ordinary skill in the art would be aware that Applicant was in possession of the claimed genus.

The specification does not provide an adequate description of the structure of the antibodies such that the skilled artisan would be aware that Applicant was in possession of the genera of claimed antibodies. Further, the specification does not adequately describe operative embodiments of the claims in their full scope. There are no readily identifiable embodiments in the specification that provide a sufficient description of the claimed components together in one composition. While "examples explicitly covering the full scope of the claim language" typically will not be required, a sufficient number of representative species must be included to "demonstrate that the patentee possessed the full scope of the [claimed] invention." *Lizardtech v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005).

In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features (see, *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1895 (Fed. Cir. 2004); accord *Ex Parte Kubin*, 2007-0819, BPAI 31 May 2007,

opinion at p. 16, paragraph 1); and *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, ___ F.3d __ (Fed. Cir. 2010), especially Slip Op. at pp. 21-23 and 27-28).

Provisional Obviousness-Type Double Patenting Rejection

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claim 121 and 198 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claims 1-7, 10, and 13 of copending Application No. 12/527218.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to antibodies against the TSHR, including monoclonal antibodies and fragments thereof, wherein the antibody competes for binding with to the TSH receptor. cAMP stimulation is taught in the specification at pp. 16, 17, 32, and 33. Applicant is reminded that MPEP § 804 (II) states, "When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not

be used as prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992). This does not mean that one is precluded from all use of the patent disclosure." (Emphasis added). "Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970)

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647